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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,449

Applicant(s)

BLOMQUIST, MICHAEL L.

Examiner

Zoila E. Cabrera

Art Unit

2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 102 rejection with respect to claims 1-25 has been maintained.

Claim Rejections - 35 USC § 102

2. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by **Estes et al. (US 2003/0114836)**.

Claims 1-25 are so broad as to read in **Estes**, who discloses a medication delivery system and monitor comprising:

With respect to claims 1-7, **Estes** discloses,

- a method of programming an ambulatory infusion pump from a computer, the ambulatory infusion pump programmed to execute a delivery program, the delivery program being driven by operating parameters (Fig. 1-2), the method comprising: generating a table on the computer, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program (Fig. 3A, element 300; Fig. 5, Alarm/Event Marker Table, i.e., the Table has rows that includes a plurality of cells such as the cell where the time is indicated, "12:58 AM" and the cell "Bolus Est."); entering an operating parameter into at least one of the cells (Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been**

logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**", [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage"; [0040] lines 1-3 and 8-10); and downloading the operating parameters into the pump (Page 6, [0060], lines 6-8, i.e., "The event markers can be logged into the pump and stored for later downloading or entered directly into the running software program"; 0035, lines 1-7);

- the table includes a plurality of rows, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump (Fig. 5, Alarm/Event Marker Table);
- at least one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM);
- the pump has memory and runs a delivery program and downloading the operating parameters includes downloading the operating parameters into the pump includes downloading the operating parameters into the memory (0035, lines 1-7; Fig. 1, element 106; Fig. 2, element 132, 100);
- the pump is programmed to run a delivery program, the method further comprising running the delivery program, thereby executing the operating parameters (Fig. 6);

- the pump has memory and is programmed to run a delivery program, the method further comprising: downloading all rows of operating parameters to the infusion pump; and storing the operating parameters in the memory (0035, lines 1-7; Fig. 1-2, elements 106, 132; Fig. 3A, element 300);
- 7. The method of claim 6 further comprising: selecting one unique identifying name (Fig. 6, i.e., BOLUS, SUSPEND, or BASAL); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (Fig. 6, i.e., SUSPEND).

As for claim 8, **Estes** discloses

- a method of operating a pump, the pump having a memory and a pump mechanism, the method comprising: receiving from a computer, a plurality of data sets, each data set containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**"; [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage"); storing the plurality of data sets in memory (Fig. 1, element 106); selecting one of the plurality of data sets (fig. 6, SUSPEND, BOLUS, BASAL); and running a delivery program wherein the delivery program executes the operating parameters in the selected

one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (Fig. 6, BOLUS DELIVERY).

With respect to claims 9-11, **Estes** discloses,

- an apparatus for programming an infusion pump, the pump programmed to execute a delivery program, the delivery program programmed to process operating parameters, the operating parameters defining operating of the pump (Fig. 6), the apparatus comprising: a data port; a data entry device (Fig. 2, elements 132, 130); and a processor in data communication with the data port and the data entry device (Fig. 1, element 102), the processor programmed to (a) generate a table, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program (Fig. 3A, element 300; Fig. 5, Alarm/Event Marker Table); (b) receive data from the data entry device (Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**"; [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage") and display the data in one or more of the cells (Fig. 1, elements 108, 114; Fig. 5, Alarm/Event Marker Table; Page 6, [0059]-[0061]); and (c) download the operating parameters displayed in the cells to the infusion pump (Fig. 5, i.e., Susp. On 2:00 pm; Page 6, [0060], lines 6-8, i.e., "The event markers can be logged into the

pump and stored for later downloading or entered directly into the running software program”);

- the processor is further programmed to generate a plurality of rows in the table, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump (Fig. 5, Alarm/Event Marker Table);
- each row in the table includes at least one cell configured to receive a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM).

As for claims 12-18, **Estes** discloses,

- a method of operating an infusion pump for delivering a therapeutic agent into the body of a user, the infusion pump being programmable and including memory, the infusion pump being programmed to run a delivery program, the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (Figs. 1-2, 5 and 6), the method comprising: storing a data set in the memory, the data set including a set of operating parameters defining a delivery schedule, at least one of the operating parameters being a uniquely identifying name (Fig. 1, element 106, Fig. 6, BOLUS, SUSPEND, BASAL; Page 6, [0058]); selecting the uniquely identifying name thereby assigning the set of operating parameters identified by the uniquely

- identifying name to the delivery program (0072, lines 1-9 and lines 15-22); and running the delivery program, the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (0073, lines 1-8; 0072, lines 1-9);
- downloading the data set to the pump from a computer (Fig. 2, elements 132, 100);
 - storing, a data set in the memory, includes storing two or more data sets in the memory, each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 6);
 - generating a menu, the menu including at least one menu item corresponding to one of the unique identifying names; and wherein selecting the unique identifying name includes selecting the menu item (Fig. 6, MAIN MENU).
 - storing a data set in the memory includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (0074, lines 8-17);
 - generating a menu includes generating a menu having at least one menu item corresponding to a unique identifying name from one data set and at least one menu item corresponding to a unique identifying, name from another data set (Fig. 6);

- switching execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (0074, lines 1-17).

As for claims 19-25, **Estes** discloses,

- an infusion pump comprising: a pump mechanism (Fig. 2, element 100); memory storing a data set (Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (Fig. 6, Bolus Delivery), at least one of the operating parameters being a uniquely identifying name (Fig. 6, BOLUS, SUSPEND, BASAL); and a processor arranged to control the pump mechanism and in data communication with the memory (Fig. 1, elements 102, 106, 124), the processor being programmed to assign the set of operating parameters to the delivery program upon selection of the uniquely identifying name and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (Fig. 6, i.e., BOLUS, SUSPEND, BASAL: 0065, lines 1-20, 0074, lines 8-17);
- a data port, the processor being further arranged to control downloading of the data set and storage of the data set into tile memory (Fig. 2, elements 132, 130, 100);
- the memory stores two or more data sets in the memory, each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 6);

- the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, wherein selecting the menu item is at least one step in beginning execution of the delivery program (Fig. 6, MAIN MENU);
- the memory stores two or more data sets, each data set including a set of operating parameters defining a separate delivery schedule (0074, lines 8-17);
- the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to a unique identifying, name from one data set and at least one unique identifying name from another data set (Fig. 6);
- the processor is further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (0074, lines 1-17).

Response to Arguments

3. Applicant's arguments filed July 6, 2004 have been fully considered but they are not persuasive.

Regarding claim 1, Applicant contends that **Estes** fails to disclose "programming a pump by entering operating parameter into at least one cell and downloading the operating parameters into the pump". Examiner disagrees because the claims are so broad as to read in **Estes** who discloses *programming a pump by entering operating parameter into at least one cell* (Fig. 5, Alarm/Event Marker Table, i.e., the Table has rows that includes a plurality of cells such as the cell where the time is indicated, "12:58

AM” and the cell “Bolus Est.”; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., “The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**”; Page 7, [0063], lines 1-13, i.e., “the time change is displayed in either 12 or 24 hr format **depending on user’s settings**”, [0064], lines 13-15, i.e., “At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage”) and *downloading the operating parameters into the pump* (Page 6, [0060], lines 6-8, i.e., “The event markers can be logged into the pump and stored for later downloading or entered directly into the running software program”; 0035, lines 1-7).

As for claim 9, Applicant contends that **Estes** does not disclose a processor programmed to receive data from the data entry device and display the data in one or more of the cells; and to download the operating parameters displayed in the cells to the infusion pump. Examiner disagrees since **Estes** teaches such limitations as discussed above with respect to claim 1.

As for claim 8, Applicant contends that **Estes** fails to teach or suggest that the pump is actually programmed and whether the pump receives a data set having a plurality of operating parameters from a computer. Examiner disagrees because **Estes** teaches such limitations (Page 6, [0060], lines 6-8, i.e., “The event markers can be logged into the pump and stored for later downloading or entered directly into the running software program”; 0035, lines 1-7, i.e. “the infusion device 100 is typically directed through programming which can be derived from a variety of possible sources.

The programming can either be entered directly into the infusion device 100, received via RF programmer or transferred from 130 or computer 132”).

As for claim 12, Applicant contends that **Estes** fails to disclose a unique name and selecting the uniquely identifying name thereby assigning the set of operating parameters identified by the uniquely identifying name to the delivery program; and running the delivery program. Examiner disagrees because **Estes** teaches such limitations (0072, lines 1-9 and lines 15-22, i.e., the infusion device has a dedicated button, touch screen button or other method, for the user to activate a “take a break bolus”, corresponding to the unique name. Please note that by activating such button an extra bolus is delivered before disconnecting from an external infusion device).

As for claim 19, Applicant contends that **Estes** fails to disclose a processor programmed to assign a set of operating parameters to a delivery program upon selection of a uniquely identifying name. Examiner disagrees because **Estes** teaches such limitations (Fig. 6, i.e., BOLUS, SUSPEND, BASAL; 0065, lines 1-20; [0074], lines 8-17; [0073], please note that unique identifying name reads on BOLUS, SUSPEND, BASAL since by selecting such names the program would act upon selection).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning communication or earlier communication from the examiner should be directed to Zoila Cabrera, whose telephone number is (703) 306-4768. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST (every other Friday).

If attempts to reach the examiner by phone fail, the examiner's supervisor, Leo Picard, can be reached on (703) 308-0538. Additionally, the fax phones for Art Unit 2125 are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at (703) 305-9600.

Zoila Cabrera
Patent Examiner
10/15/04



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